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09/641,114	08/17/2000	Peter J. Shortridge	11984-005001	4536

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EXAMINER

GELLNER, JEFFREY L

ART UNIT	PAPER NUMBER
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3643

DATE MAILED: 08/26/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/641,114

Applicant(s)

SHORTRIDGE ET AL.

Examiner

Jeffrey L. Gellner

Art Unit

3643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

PETER M. POON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600

*pmP*

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Acknowledgement is made of Applicant's Supplemental IDS entered 3 April 2002.

### ***Declaration under 37 CFR § 1.132 of Robert H. Peterson***

The declaration under 37 CFR 1.132 filed 19 June 2002 has been considered but is deemed unpersuasive. Examiner considers Poehlman to disclose general principles for seed production whether the seed is used specifically for food production or varietal increase (see Poehlman at 456 section entitled "Agricultural Extension Service"). Such concepts as planting pure seed, weed control, cleaning of planting and harvesting equipment, maintaining clean storage facilities are part and parcel of good plant husbandry practices.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, lines 4 and 6, the method is drawn to steps of "harvesting a crop containing 5% or less genetically modified seeds" and "said food product containing 5% or less genetically modified crop material," respectively. These steps imply sampling which regardless of the sample size must be accompanied by a probability level.

Art Unit: 3643

In Claim 22, lines 3,4 and 6,7, the method is drawn to steps of “certifying that a harvested genetically modified crop contains less than 5% nongenetically modified seed” and “producing genetically modified processed grain containing less than 5% non-genetically modified seeds,” respectively. These steps imply sampling which regardless of the sample size must be accompanied by a probability level.

In Claim 36, lines 6 and 7, the method is drawn to steps of “certifying that a harvested genetically modified crop contains 5% or less genetically modified seeds.” This step implies sampling which regardless of the sample size must be accompanied by a probability level.

In Claim 43, lines 8 and 9, the method is drawn to steps of “certifying that said processed food product contains 5% or less genetically modified crop material.” This step implies sampling which regardless of the sample size must be accompanied by a probability level.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-10, 13-21, 22-25, 28,29, 30-33, 36-39, and 43-51 are rejected under 35

U.S.C. 103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view of Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998).

Art Unit: 3643

As to Claim 1, Poehlman discloses the method steps of preparing a non-genetically modified processed food product (defined as, for example, at wheat grown as certified seed that is used for bread production) comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less genetically modified seed, (page 451, col. 2, sections b and d, and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified), and harvesting, processing (defined as cleaning seed with screens etc.) and certifying the crop (page 451, col. 2, section f). The purity of seed at the 5% or less level is shown by the certified seed tag (page 450, Fig. 20.2) with the row for "Other Crop Seed" and the accompanying percentage column. Not disclosed is certifying the seed contains 5% or less of genetically modified crop material. Reuters, however, discloses the motivation to certify for contamination by genetically modified crop material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman by certifying for contamination by genetically modified crop material so as to be able to sell their harvest (see Reuters).

As to Claims 2 and 3, Poehlman as modified by Reuters does not disclose the certifying step producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters to include genetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

Art Unit: 3643

As to Claims 6 and 7, Poehlman does not disclose the certifying of using an application susceptibility test for producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." Examiner takes official notice that susceptibility tests, such as ELISA and tests with antibodies, are old and notorious well known in the agronomic and plant genetics arts as a test to ID genotype or phenotype. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by using susceptibility tests to include genetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

As to Claims 8-10, not disclosed is testing for genetically modified seed prior to planting, harvesting, and processing. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by testing for genetically modified seed contamination prior to planting, harvesting and processing to ensure purity since consumer groups in Asia and the EU have generated a tide of protest against the use of genetically modified seed in foods (see Reuters).

As to Claims 13,14, 17, 20, and 21, Poehlman as modified by Reuters further disclose the nongenetically modified crop being small grains, rice, soybeans, or corn (see Poehlman pages 456 and 457).

As to Claims 15,16,18, and 19, the limitation of contamination being less than 0.1% is disclosed as described above. Not disclosed is the food product being corn sweetener or soy sauce. It would have been obvious to one of ordinary skill in the art at the time of the invention

Art Unit: 3643

to modify the method of Poehlman as modified by Reuters by making the crop into corn sweetener or soy sauce because these foods are well known uses for these crops.

As to Claims 22 and 36, Poehlman discloses the method steps of growing and harvesting a pure line of seed used for a processed food product (defined as, for example, at wheat grown as certified seed that is used for bread production) comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less off-types modified seed, (page 451, col. 2, sections b and d, and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified), and harvesting, processing (defined as cleaning seed with screens etc.) and certifying the crop (page 451, col. 2, section f). The purity of seed at the 5% or less level is shown by the certified seed tag (page 450, Fig. 20.2) with the row for "Other Crop Seed" and the accompanying percentage column. Not disclosed is certifying the seed contains 5% or less of non genetically modified crop material when the pureline is genetically modified seed. Reuters, however, discloses the motivation to certify for contamination by genetically modified crop material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman by certifying for contamination by either genetically modified or nongenetically modified crop material so as to be able to sell their harvest (see Reuters).

As to Claims 23-25, Poehlman as modified by Reuters does not disclose the certifying step producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." It would have been obvious to one of

Art Unit: 3643

ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters to include nongenetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

As to Claims 28 and 29, Poehlman does not disclose the certifying of using an application susceptibility test for producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." Examiner takes official notice that susceptibility tests, such as ELISA and tests with antibodies, are old and notorious well known in the agronomic and plant genetics arts as a test to ID genotype or phenotype. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by using susceptibility tests to include genetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

As to Claims 30-33, 37-39, not disclosed is testing for genetically modified seed prior to planting, harvesting, storing, and processing. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by testing for genetically modified seed contamination prior to planting, harvesting, including cleaning equipment before harvest and bins for storage, and processing to ensure purity since consumer groups in Asia and the EU have generated a tide of protest against the use of genetically modified seed in foods (see Reuters).

As to Claims 43, Poehlman discloses the method steps of growing and harvesting a pure line of seed used for a processed food product (defined as, for example, at wheat grown as



Art Unit: 3643

certified seed that is used for bread production) comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less off-types modified seed, (page 451, col. 2, sections b and d, and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified), and harvesting, processing (defined as cleaning seed with screens etc.) and certifying the crop (page 451, col. 2, section f). The purity of seed at the 5% or less level is shown by the certified seed tag (page 450, Fig. 20.2) with the row for "Other Crop Seed" and the accompanying percentage column. Not disclosed is inspecting the processing facility before processing the crop to maintain a product containing 5% or less of genetically modified crop material. Reuters, however, discloses the motivation to maintain pure crop material from farmer's field to food product. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman by inspecting and keeping clean the processing food plants as motivated by Reuters so that food producers can sell their product.

As to Claims 44-51, these limitations are disclosed in a similar manner as described above.

Claims 4, 5, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998) in further view of *Use of DNA in Identification* (document AU on Applicant's 1449) (hereinafter "Lander").

As to Claims 4 and 5, the limitations of Claim 1 are disclosed as described above. A certifying step using genetic testing is not disclosed. Lander, however, discloses using genetic

Art Unit: 3643

tests (DNA technology) to distinguish among genotypes (pages 1,2,and 6) and the 1 or 0.01% levels can be achieved by increasing the size of sample . It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the steps as disclosed in Poehlman as modified by Reuters by using genetic testing (DNA fingerprinting) as disclosed by Lander in the certifying step so as to increase the purity of seed planted or use as a processed seed product so as to increase yield by not having off-types.

As to Claims 26 and 27, the limitations of Claim 22 are disclosed as described above. A certifying step using genetic testing is not disclosed. Lander, however, discloses using genetic tests (DNA technology) to distinguish among genotypes (pages 1,2,and 6) and the 1 or 0.01% levels can be achieved by increasing the size of sample . It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the steps as disclosed in Poehlman as modified by Reuters by using genetic testing (DNA fingerprinting) as disclosed by Lander in the certifying step so as to increase the purity of seed planted or use as a processed seed product so as to increase yield by not having off-types.

Claims 11, 12, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998) in further in view of Montanari et al. (5,478,990; document AD on Applicant's 1449).

As to Claim 11, the limitations of Claim 1 are disclosed as described above. Not disclosed is the use of lot ID numbers which track the lot during processing. Montanari et al., however, discloses the use of ID tracking of food products from point of origin (see abstract). It

Art Unit: 3643

would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by using a tracking ID from point of origin through the processing phase so as to track contaminants such as pathogens (see abstract of Montanari et al.)

As to Claim 12, Poehlman as modified by Reuters as further modified by Montanari et al. further disclose establishing an ID number when the crop is harvested (see abstract of Montanari et al.)

As to Claim 34, the limitations of Claim 1 are disclosed as described above. Not disclosed is the use of lot ID numbers which track the lot during processing. Montanari et al., however, discloses the use of ID tracking of food products from point of origin (see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by using a tracking ID from point of origin through the processing phase so as to track contaminants such as pathogens (see abstract of Montanari et al.)

As to Claim 35, Poehlman as modified by Reuters as further modified by Montanari et al. further disclose establishing an ID number when the crop is harvested (see abstract of Montanari et al.)

### ***Response to Arguments***

This response is to arguments raised in Applicant's Response entered 12 January July 2002 as paper no. 12. The Applicant's arguments have been fully considered but they are not persuasive.

Art Unit: 3643

The crux of Applicant's argument is that ❶ Poehlman's visual screening procedures are inadequate for distinguishing between GMO and nonGMO crops and processed grain (Response page 8 last para.); ❷ Poehlman does not disclose or suggest the production, processing, and marketing of nonGMO processed grain and possible contamination with GMO grain because Poehlman deals with breeder seed and seed certification and, hence, is nonanalogous art (Response page 8 last para., page 10 2<sup>nd</sup> para., page 12 1<sup>st</sup> complete para.); ❸ Poehlman does not disclose or suggest a method for detecting contamination in nonGMO grain by GMO seed because GMO seed is not an "off-type," "Other Seed," "Weed Seed," or "Noxious Seed" (Response page 9 2<sup>nd</sup> para.); ❹ Poehlman cannot suggest a method for preparing nongenetically modified processed grain having low level of contamination by genetically modified seed because Poehlman's publishing date predates genetically modified seed (Response page 9 last para.); ❺ Reuters provides no motivation to combine with Poehlman (Response page 10 1<sup>st</sup> para.); ❻ Neither Poehlman or Reuters or then combined provide a reasonable expectation of success in segregating GMO and nonGMO seed (Response page 11 1<sup>st</sup> complete para.); ❼ Lander provides no motivation to combine with Poehlman and Reuters and no reasonable expectation of success (Response page 13 1<sup>st</sup> complete para.); ❽ Examiner was incorrect in statements about increasing power of the sampling by increasing the number of loci sampled (Response page 13 last para.); and, ❾ Montanari is directed towards identifying animals and there exists no motivation to combine with Poehlman and Reuters (Response page 14 penultimate para.).

Art Unit: 3643

As to ❶ Examiner considers Poehlman's visual screening procedures to be adequate to distinguish between genotypes when they cause different phenotypes regardless of the seed being GMO or nonGMO.

As to ❷ Examiner considers Poehlman to disclose methods for keeping seed pure for both breeder and farmer seed. Examiner considers the 1<sup>st</sup> sentence (specifically, "offers useful service by encouraging the general use of pure seed of improved varieties throughout the state") of the section entitled "Agricultural Extension Services" on page 456 to have within its ambit the concepts of keeping equipment and storage facilities clean, planting and harvesting pure seed, and actively maintaining pure seed.

As to ❸ Examiner considers GMO seed in nonGMO seed to be an off-type.

As to ❹ Although Poehlman's publishing date predates the release of GMO seed Poehlman does disclose the concept of maintaining pure seed. Examiner uses Poehlman for its concept and methods of maintaining pure seed and, consequently, eliminating other genotypes whether they be GMO or nonGMO.

As to ❺ Examiner considers the combination of Poehlman and Reuters to be proper because Poehlman discloses the concept and methods of maintaining pure seed and Reuters discloses the concept of the need to guard against contamination by GMOs. Both references have a goal of maintaining pure seed. Further, it would be obvious to one of ordinary skill in the art at the time of the invention to expand the methods of Poehlman to include maintenance against contamination by GMOs.

Art Unit: 3643

As to ⑥ references can be combined if there is a reasonable expectation of success (see MPEP 2143.02). Here there is a reasonable expectation of success because Poehlman's methods have been successful in the past and GMOs are just another type of off-type seed.

As to ⑦ Examiner considers the combination of Poehlman/Reuters with Lander to be proper because Lander discloses a method of separating phenotypes by comparing genotypes with DNA fingerprinting. Lander's goal is, in essence, the same goal as that of Poehlman and Reuters achieved by a different means.

As to ⑧ Examiner withdraws any objection or rejection concerning the power to reduce type I errors by increasing the number of loci sampled.

As to ⑨ Examiner considers Montanari to disclose the concept of tracking particular products from point of origin. Although Montanari's ID is used with animals the goal is compatible with the goal of Poehlman - maintaining pure seed. Examiner considers it proper to combine the concept and methods of maintaining pure seed lots with the concept and method to ensuring the documented history of products.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeffrey L. Gellner whose telephone number is 703.305.0053. The Examiner can normally be reached Monday through Thursday from 8:30 am to 4:00 pm. The Examiner can also be reached on alternate Fridays.

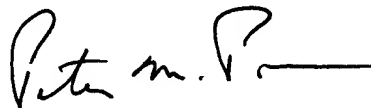
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Peter Poon, can be reached at 703.308.2574. The fax phone numbers for the Technology Center where this application or proceeding is assigned are 703.305.7687, 703.305.3597, and 703.306.4195.

Art Unit: 3643

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1113.

A handwritten signature in black ink, appearing to read 'JL G'.

Jeffrey L. Gellner

A handwritten signature in black ink, appearing to read 'Peter M. Poon'.

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